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Opinion on Premium IOLs in Phacoemulsification Surgeries

Parecer acerca de LIOs Premium em Cirurgias de Facoemulsificação

Parecer acerca de LIOs Premium en Cirurgías de Facoemulsificación

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ABSTRACT

On June 7, 2018, the Brazilian Cataract and Refractive Surgery Association (ABCCR) and the Brazilian Council of Ophthalmology (CBO) issued an opinion on the use of premium intraocular lenses in phacoemulsification surgeries in order to mediate conflicts between the ophthalmologic class and the private healthcare insurance providers. Here we reproduce the document in its entirety.

Keywords: Lenses Intraocular; Cataract; Supplemental Health; Health Maintenance Organizations.

RESUMO

Em 07 de junho de 2018 a Associação Brasileira de Catarata e Cirurgia Refrativa (ABCCR) e Conselho Brasileiro de Oftalmologia (CBO) emitiram parecer acerca da utilização de lentes intraoculares Premium nas cirurgias de facoemulsificação com a finalidade de mediar os conflitos existentes entre a classe oftalmológica e as operadoras de planos privados de assistência à saúde. Aqui reproduzimos o documento na íntegra.

Palavras-chave: Lentes Intraoculares; Catarata; Saúde Suplementar, Sistemas Pré-Pagos de Saúde.

RESUMEN

El 07 de junio de 2018 la Asociación Brasileña de Catarata y Cirugía Refractiva (ABCCR, por sus siglas en portugués) y el Consejo Brasileño de Oftalmología (CBO) emitieron un parecer acerca de la utilización de lentes intraoculares Premium en las cirugías de facoemulsificación, con la finalidad de mediar los conflictos existentes entre la clase oftalmológica y las operadoras de seguros privados de asistencia a la salud. Aquí, reproducimos el documento íntegro.

Palabras Clave: Lentes Intraoculares; Catarata; Salud Complementaria; Sistemas Prepagos de Salud.

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1. HISTORICAL CONTEXT

Firstly, it is important to refer the discussions on the subject that culminated in the current stand of the Brazilian Council of Ophthalmology (Conselho Brasileiro de Oftalmologia [CBO]):

"INTRAOCULAR LENSES" - "There have been several problems caused by healthcare insurance providers, compromising the safety of surgeries and the beneficiaries' right to opt for better materials, as well as interfering with the role of surgical centers to provide quality material for ophthalmic surgeries.

Some providers purchased batches of lower-quality intraocular lenses (IOLs), demanding that their accredited ophthalmologists implanted them. Patients were even denied their right to opt for another IOL of better quality or one that offered more optical resources.

Others provided only one IOL, disregarding the possibility that it could be contaminated, lose its handle, or tear during handling. All of them believed that problems caused by perioperative complications, such as posterior capsule rupture and loss of support, among others, should be solved by surgeons, at their expense. Others, in addition to providing the IOL directly to the patient, also provided viscoelastic substances that the patient was supposed to take home and then to the surgical center, giving rise to problems due to inappropriate storage.

Even the providers who supplied good quality IOLs requested by their accredited surgeons had difficulty in managing the delivery of hundreds of IOLs requested weekly, which led to last-minute cancellation of surgeries, creating friction with patients and their relatives.

These and other less frequent problems, but equally worrisome, led the Rio de Janeiro State Cooperative of Administrative Services in Ophthalmology (Cooperativa Estadual de Serviços Administrativos em Oftalmologia do Rio de Janeiro [COOESO-RJ]) to request the action of the Consumer Protection Division of the Public Prosecutor's Office of Rio de Janeiro in 2007. A Conduct Adjustment Agreement (Termo de Ajuste de Conduta [TAC]) was made with the healthcare insurance providers.

The approved decision implied that healthcare insurance providers should refrain from supplying material and medication to physicians and surgical centers for ophthalmic surgeries, as it was made clear that the responsibility for the choice, delivery, and use of medicines, ortheses, and prosthetics belongs to physicians and surgical centers. Therefore, the approved TAC established that IOLs, viscoelastic substances, and phacoemulsification and vitrectomy kits must not be shipped by the providers.

Based on this agreement, the providers had to establish service contracts with the surgical centers, negotiating values to reimburse the material used - the so-called "packages" of fees, materials, and medication. Such packages cannot include medical fees nor the cost of IOLs.

With regard to IOLs, it was agreed that each provider would establish a costing value to cover their use.

Therefore, it was made clear that, based on the TAC signed and approved by the Public Prosecutor's Office, healthcare insurance providers would no longer provide IOLs, and they were only required to define a costing value that would cover the acquisition of ANVISA-approved good-quality IOLs, exclusively to treat cataracts". (text by Dr Nelson T. Louzada - President of FeCOOESO *in* www.cooeso.com.br/)

2. CLASSIFICATION OF IOLS

Several IOLs are available in the market. For ease of understanding, they can be classified into five types:

- Monofocal Lenses: these are the most commonly used lenses, both in private and public healthcare services. As the name implies, these lenses only correct myopia or hypermetropia, because they have only one field of vision;
- Multifocal Lenses: these are high-technology (premium) lenses that correct more than one field of vision, *i.e.*, the same lens corrects far, intermediate, and near vision, allowing greater visual independence. Depending on the reading situations and the patient's level of requirement, glasses may still be necessary but much less frequently. Because their manufacture involves more advanced technology, the cost of multifocal lenses is higher;
- Monofocal Toric Lenses: these are also considered high-technology (premium) lenses. They effectively correct astigmatism greater than 0.75 D. Because their manufacture involves more advanced technology, their cost is also higher;
- Multifocal Toric Lenses: They combine both technologies, because multifocal lenses have no satisfactory effect in the presence of uncorrected astigmatism. They are indicated for patients who desire multifocality

and have corneal astigmatism greater than 0.75 D. Because they combine two premium technologies, their cost is high among intraocular lenses;

- Extended Focus Lenses: lenses that increase the depth of focus and decrease dependence on glasses, despite not being multifocal lenses. They are also considered high-technology (premium) lenses. As their manufacture involves more advanced technology, their cost is also higher;
- Pseudoaccommodating Lenses: they are also considered high-technology (premium) lenses. They have the ability to simulate the natural accommodation of the lens, correcting far, intermediate, and near vision. As their construction involves higher technology, their costs are also higher.

Note: The latter lenses are not currently available in Brazil.

All types of IOLs described above may also be classified as spherical, which do not correct spherical aberrations, and as aspheric, which correct spherical aberrations and, in certain cases, lead to better vision. As their manufacture involves more advanced technology, aspheric lenses are considered premium lenses, and their cost is also higher.

In order to indicate the type of IOL to be used, a complete ophthalmic examination that takes into account the lifestyle and the needs of the patient is required.

3. OPINION

The Normative Resolution ANS nº 428 of 07/11/2017, which establishes the guidelines of Supplementary Healthcare and updates the List of Procedures and Events in Healthcare, provides for the surgery for extraction of a cataractous lens (cataract surgery). Thus, coverage for this event is mandatory for private healthcare insurance plans. Considering that the placement of ortheses and prostheses requiring surgical procedures is obligatorily covered in plans regulated by Law no. 9,656/1998, IOLs would meet the same criterion.

However, the CBO has issued an opinion on the procedures of informing about and charging for the IOLs available in the various modalities of cataract surgeries to be put before the patients, when appropriate, as follows:

"Cataract is a lens opacity that can lead to a reduction of its optical quality (ICD 9 #366). The primary purpose of cataract surgery with intraocular lens implantation is to replace the opaque lens with a prosthesis (intraocular lens). These are the "Facectomy with intraocular lens with phacoemulsification" (3.03.06.02-7) or "Facectomy with intraocular lens without phacoemulsification" (3.03.06.03-5) procedures.

Another possibility is a cataract surgery using intraocular lenses with special features that may correct other visual changes uncorrected with spherical monofocal intraocular lenses, such as toric, bifocal, multifocal, accommodative, and aspherical intraocular lenses.

Considering that facectomy with intraocular lens implant, with or without phacoemulsification, is included in the List of Procedures and Events in Healthcare of the National Supplementary Health Agency (Agência Nacional de Saúde Suplementar [ANS]), healthcare insurance providers are responsible for paying for the purchase of ANVISA-approved spherical monofocal intraocular lens. This coverage does not extend to the use of intraocular lenses with special characteristics that can correct higher-order aberrations, astigmatism, and presbyopia.

In this case, the difference between the cost of spherical intraocular lenses paid by healthcare insurance providers and of those with special characteristics is to be paid by the patient, who should be aware of this cost and sign an informed consent form.

The CBO once again indicates to its associates and the general public that its website features templates of documents on best practices in implanting and charging for special-feature intraocular lenses."

It should be clarified that the CBO has questioned the ANS' Technical Opinion21/GEAS/GGRAS/DIPRO/2016 about the subject through the CSS-Pres. Official Letter No. 200-2017 Technical Opinion No. 21- GEAS-GGRAS-DIPRO-2016. In view of this fact, the agency issued Technical Opinion22/GEAS/GGRAS/DIPRO/2018, which emphasizes that "*strict treatment of astigmatism, myopia, hypermetropia, presbyopia, and keratoconus through intraocular lens implantation is not included in the current List; therefore, their coverage is not mandatory*."

In view of the above, the CBO acknowledges the right of providers to establish a limit for the cost of IOLs, letting patients and physicians decide on the differences when they exist. Therefore, the most appropriate conduct would be to establish a reference value that ensures the acquisition of a good monofocal spherical IOL (ANVISA-approved), thus assuming responsibility for a given value for the prosthesis, not necessarily being required to cover the entire cost of a different IOL. The cost difference for the acquisition of a premium IOL is to be paid by the patient, who should be aware of this cost and sign an informed consent form (attached to this opinion).

In turn, the requesting provider must provide to the patient information regarding the reasons for the indication of premium lens if that is the case.

To minimize the risk of judicialization, physicians must fully inform the patients.

4. CONCLUSIONS

This opinion suggests that private healthcare insurance PROVIDERS should establish a limit value for the acquisition of spherical ANVISA-approved IOLs, and advise their accredited ophthalmologists to adopt an Informed Consent Form (template attached).

Thus, any IOL that is deemed premium will not be considered, in line with the terms of this opinion, as being of mandatory coverage. Furthermore, the multifocal characteristic of a lens also allows the IOL to correct presbyopia, which could be achieved with the use of orthesis (glasses).

This is the opinion, barring better judgment.

São Paulo, June 7, 2018.

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